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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/766,711 | 01/27/2004 | W. James Jackson | 2479.004003/EJH/C-K | 4900 |

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| EXAMINER |
|---|
| BASKAR, PADMAVATHI |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 31 DAYS | 02/23/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/766,711 | JACKSON ET AL. | |
| | Examiner | Art Unit | |
| | Padmavathi v. Baskar | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2, 27-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2, 27-82* _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. The response to restriction filed 11/17/06 to the Office Action of 8/17/06 is acknowledged and has been entered. Applicant's election with traverse of Group 1, isolated polypeptide, species, SEQ ID NO:2, claims 2, 21, 22 and newly added claims 27-82 is acknowledged. The traversal is on the ground(s) that the inventions have not been shown to be independent and the examination of all groups would not impose a serious burden on the examiner. This is not found persuasive. MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the various groups are distinct for the reasons previously set forth. As to the question of burden of search, the inventions are classified differently, necessitating different searches in the US Patent shoes. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search (art here is cancer immunotherapy). Different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

***Status of claims***

2. Claims 1, 3-12, 14-15, 17-20 and 23-26 have been canceled.
Claims 2 has been amended.
Claims 27-82 have been added.
Claims 2, 13, 16, 21, 22, 27-82 are pending in the application.
Claim 2 is withdrawn from consideration because applicant elected a single sequence, SEQ ID NO:2 but the amended claim 2 is not drawn to SEQ ID NO:2, but rather is drawn to an isolated polypeptide comprising an amino acid sequence at least 95% identical to SEQ ID NO:3, 17 or 25-37 – therefore. Since the claim is not drawn to the elected invention, it has properly been withdrawn from consideration.
Claim 13 is withdrawn as it is drawn to a polypeptide encoded by pta-3719 which encodes SEQ ID NO:15.
Claim 21 is withdrawn as it is drawn to SEQ ID NOS 23 or 24.
Claim 22 is withdrawn as it is drawn to SEQ ID NOS 15 or 16.

Claims that are to be examined are 13, 16, 73, 21 and 22 , only as it is drawn to SEQ ID NO:1, encoding SEQ ID NO:2 , and the dependent claims that read on elected invention SEQ.ID.NO:2 only, THAT IS CLAIMS 27-82.

However, upon review and reconsideration and in view of the newly amended claims, it is found that the elected invention contains claims directed to the following patentably distinct species of the claimed invention:

3. Claims 27, 49 and 73 are generic to a plurality of disclosed patentably distinct species comprising variants of SEQ ID NO:2, wherein the variants are (1) polypeptides comprising fragments of SEQ ID NO:2, wherein the fragments are (a) amino acids 29-253 of SEQ ID NO:2/ a sequence at least 95% identical thereto, (b) amino acids 217-674 of SEQ ID NO:2/ a sequence at least 95% identical thereto, (c) amino acids 688-1012 of SEQ ID NO:2/ a sequence at least 95% identical thereto, (d) amino acids 29-1012 of SEQ ID NO:2/ a sequence at least 95% identical thereto, (2) polypeptides encoded by DNA sequence that are complementary to the nucleotide sequence encoding SEQ ID NO:2.

Further, claims 27-82 are directed to the following patentably distinct species:

(A) Heterologous polypeptide is selected from the group consisting of a pre or pro sequence, an affinity purification peptide, a heterologous immunogenic peptide, and a combination of two or more of said heterologous polypeptides

(B) Adjuvant is selected from the group consisting of alum, mLT, QS21, MPS, Freund's complete adjuvant, and a combination of two or more of said adjuvants.

(C) Targeting molecule is selected from the group consisting of vitamin B 12, bacterial toxins or fragments thereof, monoclonal antibodies, proteins, nucleic acids, carbohydrates, and a combination of two or more of said targeting molecules.

(D) Composition which is formulated as a microparticle, a capsule, a liposome preparation, or an emulsion

(E) Composition which induces a humoral immune response (HIR) or cell mediated immune response (CMI) .

(F) Mammal or a bird.

The species with in heterologous polypeptides, adjuvants, targeting molecules, composition formulations, immune responses, mammal or bird as stated above are independent or distinct because each species is structurally and functionally different and distinct that result in a different function such as HIR or

CMI in a mammal or bird. .

Therefore, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted . If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

5. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

7. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The

Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Padma Baskar Ph.D.